Official Title and Summary

Prepared by the Attorney General

PRESCRIPTION DRUG DISCOUNTS. STATE-NEGOTIATED REBATES. INITIATIVE STATUTE.

- Provides for prescription drug discounts to Californians who qualify based on income-related standards, to be funded through rebates from participating drug manufacturers negotiated by California Department of
- Prohibits new Medi-Cal contracts with manufacturers not providing the Medicaid best price to this program, except for drugs without therapeutic equivalent.
- Rebates must be deposited in State Treasury fund, used only to reimburse pharmacies for discounts and to offset costs of administration.
- At least 95% of rebates must go to fund discounts.
- Establishes oversight board.
- Makes prescription drug profiteering, as described, unlawful.

SUMMARY OF LEGISLATIVE ANALYST'S ESTIMATE OF NET STATE AND LOCAL GOVERNMENT FISCAL IMPACT:

- One-time and ongoing state costs, potentially in the low tens of millions of dollars annually, for administration and outreach activities for a new drug discount program. A significant share of these costs would probably be borne by the state General Fund.
- State costs, potentially in the low tens of millions of dollars, to cover the funding gap between when drug rebates are collected by the state and when the state pays funds to pharmacies for drug discounts provided to consumers. Any such costs not covered through advance rebate payments from drug makers would be borne by the state General Fund.
- Unknown potentially significant net costs or savings as a result of provisions linking state Medi-Cal rebate contracts and the new drug discount program.
- Unknown potentially significant savings for state and county health programs due to the availability of drug discounts.
- Unknown costs and revenues from the provisions regarding lawsuits over profiteering on drug sales.
- Potential unknown effects on state revenues and expenditures from changes in prices and quantities of drugs sold in California.

ANALYSIS BY THE LEGISLATIVE ANALYST

BACKGROUND

Prescription Drug Coverage. Currently, several state and federal programs provide prescription drug coverage to eligible individuals. The state's Medi-Cal Program, which is administered by the Department of Health Services (DHS), provides prescription drugs for low-income children and adults. The state's Managed Risk Medical Insurance Board administers the Healthy Families Program, which provides prescription drugs for children in low-income and moderate-income families who do not qualify for Medi-Cal.

Beginning January 2006, the federal government will provide prescription drug coverage to persons also enrolled in Medicare, a federal health program for elderly and disabled persons. (This would include

some persons enrolled in Medi-Cal who are also enrolled in Medicare.) Various other programs funded with state or federal funds also provide assistance to help pay part or all of the cost of drugs for specified individuals.

In addition, many Californians receive coverage for prescription drugs through private insurance that is purchased by individuals or provided by their employer or the employer of a member of their family.

Drug Discounts for Individuals. California, a number of other states, and private associations and drug makers have established drug discount programs. These programs help certain consumers, including individuals who are not eligible for state and federal programs that provide drug coverage, purchase prescription drugs at reduced prices. Current California law, for example, requires retail pharmacies to sell prescription drugs at a discount to elderly and disabled persons enrolled in Medicare as a condition of a pharmacy's participation in the Medi-Cal Program.

Drug Rebates for Medi-Cal. Federal law requires that drug makers provide rebates on their drugs to state Medicaid programs, such as Medi-Cal, so that the net price paid would be lower than that paid by most private purchasers. Also, the state negotiates for additional rebates from drug makers in exchange for giving the drugs made by those companies preferred status in the Medi-Cal Program. Preferred status means that doctors may prescribe a particular drug without receiving advance approval from the state. The rebates received by the state help reduce its costs for drugs for persons enrolled in Medi-Cal.

Linking Medicaid to Other State Programs. Some states have sought to obtain greater discounts from drug makers on prescription drugs for other health programs, including drug discount programs, by linking them to their Medicaid Programs. This approach involves allowing drug makers' products to have preferred status in their Medicaid Program only if the drug maker provides discounts or rebates on drugs for their non-Medicaid Programs. A 2003 U.S. Supreme Court decision has been interpreted to mean that states may do this as long as their

actions would further the goals of Medicaid, such as providing assistance to individuals who might otherwise end up on the Medicaid rolls, and as long as they seek and obtain prior federal approval for their actions.

PROPOSAL

This proposition creates a new state drug discount program to reduce the costs that certain residents of the state would pay for prescription drugs purchased at pharmacies. The major components of the measure are outlined below.

Discount Card Program. Under the new drug discount program, eligible persons could obtain a card that would qualify them for discounts on their drug purchases at pharmacies. The program would be open to California residents in families with an income at or below 400 percent of the federal poverty level—up to about \$38,000 a year for an individual or about \$77,000 for a family of four. Discount cards would also be available to some persons in families with higher incomes with medical expenses at or above 5 percent of their family's income. Persons enrolled in Medicare could obtain discount cards for drugs not covered by Medicare. Persons could not participate in the new drug discount program if they receive their drug coverage from the Medi-Cal or Healthy Families Programs.

The new drug discount program would be administered by DHS, which could contract with a private vendor for assistance. Participants would enroll in the program by paying a \$10 fee, and would pay an annual renewal fee of the same amount. Eligible persons could enroll or reenroll in the program at any pharmacy, doctor's office, or clinic which chose to participate in the drug discount program. Applications and renewals could also be handled through an Internet Web site or through a telephone call center. The DHS would review applications and mail the drug discount cards to eligible persons, usually within four days.

The state would seek two types of discounts in order to obtain lower prices for persons with the new drug discount cards. First, pharmacies that voluntarily chose to participate in the program

would agree to sell prescription drugs to cardholders at an agreed-upon discount negotiated in advance with the state. In addition, pharmacies would further discount the price to reflect any rebates the state negotiated with drug makers. (The pharmacies would subsequently be reimbursed for this second type of discount with rebates collected by the state from the drug makers.)

Linkage to Medi-Cal Program. The measure links this new drug discount program to the Medi-Cal Program for the purpose of obtaining reduced prices on drugs purchased with drug discount cards. Specifically, the measure states that DHS may not contract with a drug maker for the Medi-Cal Program if that drug maker does not sell its drugs at a reduced price to the new drug discount program. This includes contracts by which the state obtains rebates on drugs in exchange for giving those drugs preferred status in Medi-Cal. If a drug maker does not agree to such a contract for its drugs, its drugs may be subject to an existing requirement that a doctor receive prior approval from the state before such drugs are prescribed for a Medi-Cal patient. In addition, this measure provides that the names of drug makers and whether they entered into such contracts shall be released to the public.

The measure specifies that these requirements would be implemented consistent with federal law. It further specifies that these provisions would not apply to a drug if there were not another equivalent drug available. Also, the measure provides that a Medi-Cal beneficiary who has already been prescribed a drug would be allowed to continue to receive it without prior approval.

Private Drug Discount Programs. The measure directs DHS to implement agreements with drug discount programs operated by drug makers and other private groups so that the discount cards would automatically provide consumers with access to the best discount available to them for a particular drug purchase.

New State Advisory Board. The measure creates a new nine-member Prescription Drug Advisory Board to review the access that state residents have to prescription drugs as well as the pricing of those drugs, and to provide advice and regular reports on drug pricing issues to state officials.

Outreach Efforts. The measure directs DHS to conduct an outreach program to inform state residents about the new drug discount program. The outreach activities are to be coordinated with the Department of Aging, other state agencies, local agencies, and nonprofit organizations that serve residents who might be eligible for the program.

Assistance to Businesses and Labor Organizations. The measure authorizes DHS to establish a drug discount program to assist certain businesses and labor organizations that purchase health coverage for employees and their dependents. The DHS could help these organizations to reduce their drug costs by arranging for discounts on drug prices with pharmacies and seeking to negotiate rebates on drugs on behalf of employees and their dependents.

Profiteering From Drug Sales. Existing state law does not limit the prices or profits that can be earned on the sale of prescription drugs in California. This measure changes state law to make it a civil violation for drug makers and certain other specified parties to engage in profiteering from the sale of prescription drugs. The definition of profiteering includes demanding "an unconscionable price" for a drug or demanding "prices or terms that lead to any unjust and unreasonable profit." Profiteering on drugs would be subject to prosecution by the Attorney General or through a lawsuit filed by any person acting in the interests of itself, its members, or the general public. Violators could be penalized in the amount of \$100,000 or triple the amount of damages, whichever was greater, plus legal costs.

Related Provisions in Proposition 78. Proposition 78 on this ballot also establishes a new state drug discount program. The key differences between Proposition 78 and Proposition 79 are shown in Figure 1.

The State Constitution provides that if a particular provision of a proposition that has been approved by the voters is in conflict with a particular provision of another proposition approved by the voters, only the provision in the measure with the higher number of yes votes would take effect. Proposition 78, another measure on the ballot, specifies that its provisions would go into effect in their entirety, and that none of the provisions of a competing measure such as

	Proposition 78	Proposition 79
General eligibility requirements	 California residents in families with an income at or below 300 percent of the federal poverty level. (About \$29,000 annually for an individual and \$58,000 for a family of four.) No such provision. 	 California residents in families with an income at or below 400 percent of the federal poverty level. (About \$38,000 annually for an individual and \$77,000 for a family of four.) Also, persons in families with medical expenses at or above 5 percent of thei family's income.
Persons excluded from coverage	 Persons with outpatient prescription drug coverage through Medi-Cal, Healthy Families, a third-party payer, or a health plan or drug discount program supported with state or federal funds (except Medicare beneficiaries). Certain persons with drug coverage, during the three-month period prior to the month the person applied for a drug discount card. 	 Persons with outpatient prescription drug coverage through Medi-Cal or Healthy Families (except Medicare beneficiaries). No such provision.
Application and renewal fee	• \$15 per year.	• \$10 per year.
Method of obtaining rebates from drug makers	Negotiated with drug makers.No such provision.	 Negotiated with drug makers. Subject to federal approval, links new drug discount program to Medi-Cal for the purpose of obtaining rebates on drugs.
Assistance to business and labor organizations	No such provision.	 Establishes drug discount program to assist certain business and labor entities.
Prescription Drug Advisory Board	No such provision.	 Creates new nine-member panel to review the access to and pricing of drugs.
Lawsuits over drug profiteering law	No such provision.	 Changes state law to make it a civil violation for a drug maker to engage in profiteering from the sale of drugs.

Proposition 79 would take effect, if Proposition 78 received the higher number of yes votes.

FISCAL EFFECTS

This measure could have a number of fiscal effects on state and local government. We discuss several major factors below that could result in costs or savings.

State Costs for Administration and Outreach Activities. The DHS, the Department of Aging, and the newly created Prescription Drug Advisory Board would, in combination, incur significant startup costs, as well as ongoing costs, for administrative and outreach activities to implement the new drug discount program created by this proposition.

This could include administrative costs to:

- Establish the new program, including any new information technology systems that would be needed for its operation.
- Operate the Internet Web site and the call center to receive applications for drug discount cards.
- Process applications and renewals of drug discount cards.
- Negotiate and collect rebates from drug manufacturers and make advance rebate payments to pharmacies.
- Assist business and labor organizations in obtaining drug discounts.
- Coordinate the state's drug discount program with other private drug discount programs.

As noted earlier, this measure links its new drug discount program to Medi-Cal contracts that permit some drugs to be prescribed to Medi-Cal patients without prior approval by the state. To the extent that additional prior approvals of drugs are required for Medi-Cal patients as a result of these provisions, DHS would incur additional administrative costs to process these requests.

The state would also incur additional costs for the proposed outreach activities, potentially including costs for radio or television advertising, written materials, and other promotional efforts to make consumers aware of the drug discount program.

In the aggregate, these administrative and outreach costs—including costs for business and

labor assistance as well as processing additional Medi-Cal requests for prior approval of drug prescriptions—would probably range in the low tens of millions of dollars annually. The exact fiscal effect would depend primarily on the extent of outreach efforts and the number of consumers who chose to participate in the drug discount program.

These state costs could be partly offset by (1) up to a 5 percent share of the rebates collected from drug makers, (2) any private donations received for the support of outreach efforts, and (3) a portion of the enrollment fees collected for the program. Our analysis indicates that the 5 percent share of rebate funding alone is unlikely to offset these state costs. The amount of donations that the state would receive on an ongoing basis for outreach activities is unknown. The amount of fee revenue that would be collected by the state is also unknown. In view of the above, it appears likely that a significant share of the cost of this program would be borne by the state General Fund.

Costs for "Float." This measure requires the state to reimburse pharmacies for part of the amount that they discounted their drugs. This reimbursement reflects discounts for which the state receives rebates from drug makers.

The reimbursement to pharmacies must be made within two weeks after their claims are filed with the state. However, drug makers are required by the measure to pay rebates to the state on at least a quarterly basis. This means that the state could, in many cases, pay out rebates to pharmacies before it actually collects the rebate funds from drug makers. Moreover, any disputes that arise over the actual amounts owed for rebates could further slow payments of rebate funds by drug makers to the state.

This recurring gap in funding between when rebate money is collected by the state and when the state has to pay pharmacies is commonly referred to as float. The cost of the float is unknown, but could amount to the low tens of millions of dollars, depending on the level of participation in the new drug discount program. Float costs would occur mainly in the early years of implementing this new program. After the program has been fully implemented, rebate funds collected from drug

makers should be largely sufficient to reimburse pharmacies.

This measure permits the state to enter into agreements with drug makers to collect rebate funds in advance. The amount of funding that the state would receive through such advance payments is unknown. Any float costs that exceeded these advance rebate payments would be borne by the state General Fund.

State Costs or Savings From Linking Drug Discount Programs to Medi-Cal. As noted earlier, this proposition states that DHS may not enter into a Medi-Cal contract with a drug maker that did not agree to provide discounts on the price of their drugs for the new drug discount program. This provision could result in additional costs and savings to the Medi-Cal Program depending upon future actions by the federal government, drug makers, or doctors. For example, this provision could result in the state receiving fewer drug rebates from drug makers for the Medi-Cal Program, thus resulting in costs. On the other hand, this provision could result in savings in cases in which the removal of a drug from preferred status resulted in fewer prescriptions of the drug and its replacement by a less costly medication. The net fiscal effect of this provision on the Medi-Cal Program is unknown but could be significant.

Potential Savings for State and County Health Programs. The drug discount program established under this proposition could reduce costs to the state and counties for health programs.

Absent the discounts available under such a drug discount program, some lower income individuals who lack drug coverage might forego the purchase of their prescribed drugs. Such individuals might eventually require hospitalization as a result of their untreated medical conditions, thereby adding to Medi-Cal Program costs. Other individuals might

"spend down" their financial assets on expensive drug purchases absent such discounts and become eligible for Medi-Cal. The exact amount of savings to the Medi-Cal Program from a drug discount program is unknown, but could be significant if the program enrolled a large number of consumers.

Similarly, the availability of a drug discount program could reduce costs for other state health programs. It could also do so for county indigent care by decreasing out-of-pocket drug expenses for low-income persons who require medications, thereby making them less likely to rely on county hospitals or clinics for assistance. The extent of these potential savings is unknown.

State Costs and Revenues From Provision on Profiteering From Drug Sales. This measure would have an unknown fiscal impact on state support for local trial courts, depending primarily on whether the measure increases the overall level of court workload. The number of civil cases that might result from this measure is unknown. Also, the measure could result in some additional costs for the Attorney General to prosecute profiteering cases. These costs are estimated by the Department of Justice to be less than \$1 million annually. However, these costs could be offset to the extent that the state collected revenues from civil penalties in cases where civil prosecutions were successful.

Other Fiscal Effects. This measure would affect both the prices and quantities of prescription drugs sold in California. In turn, this could affect the taxable profits of drug makers and businesses that provide health care for their employees, as well as consumers' disposable income. These changes could affect state revenues. Changes in the prices and quantities of drugs sold could affect state expenditures as well. The net impact of these factors on state revenues and expenditures is unknown.